PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference W 08-03	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/ES2003/000598	International filing date *(day/month/year)* 25.11.2003	Priority date *(day/month/year)* 25.11.2003
International Patent Classification (IPC) or national classification and IPC A61B17/64		
Applicant INSTITUTO TECHNOLOGICO DE CANARIAS, S.A. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 12 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.06.2005	02.02.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Lager, J Telephone No. +49 89 2399-2957

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/ES2003/000598

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-6	received on 18.01.2006 with letter of 05.01.2006
Claims, Numbers	
1-4	received on 18.01.2006 with letter of 05.01.2006
Drawings, Sheets	
1/4-4/4	filed with the demand

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 5-6
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/ES2003/000598

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-4
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-4
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-4
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Section V.

1. The wording of the claims is not clear, Article 6 PCT, see Section VIII below. When interpreting the "pitches (2), whose internal surface is concave, creating cylindrical segments," as "holes (2) having spherical bearing surfaces (13) creating spherical segments"; "corresponding pitches (2)" as "diameter of both spherical segments"; "pitch (11) / diametral pitch (11)" as "cylindrical hole (11)"; and several other interpretations based on figure 1, it appears that the subject-matter of claim 1 fulfils the requirements of Article 33(2)-(3) PCT for the following reasons (if such interpretations are allowable under Article 123(2) EPC in a possible later European application must be examined at a later stage):

   Document US-A-5 653 707 (=D1), representing the closest prior art, discloses an external wrist fixator form which the subject-matter of claim 1 differs in that the main articulator (1) is embodied in an extended body provided with a pair of identical holes (2) having spherical bearing surfaces (3) creating spherical segments which are connected to one another by means of an axial slot (4) in the extended body which may be narrowed by tightening a transverse screw (8) and corresponding threaded hole in the extended body in order to reduce the diameter of both spherical segments, spherical bearings (10) each having a cylindrical hole (11) are housed in the spherical bearing surfaces (3), each spherical bearing (10) having a slot (12) which is tightened around each corresponding bar (13) by tightening the screw (8), and spherical screws (14) having cylindrical holes put on each bar (13) to provide a link to each support (15).

1.1 This difference over the teaching and disclosure of D1 enables an easy tightening of the articulation by means of only tightening one screw. D1 and the other cited documents teaches at least screw-and-nut which requires two hands.

1.2 It is therefore considered that claim 1 fulfils the requirements of Article 33(2)-(3) PCT.

1.3 Claims 2-4 define preferred embodiments.

2. It appears therefore that claims 1-4 fulfil the requirements of Article 33(2)-(4) PCT.

Section VII.

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Section VIII.

1. The wording of the claims is completely unclear, Article 6 PCT. The unclarity makes the interpretation of the claims difficult and almost impossible.

   The scope of protection afforded by the claims remains obscure. The assessment under Section V above has been done with support of figure 1.

AMENDED VERSION UNDER Art 34(2)(b)

EXTERNAL WRIST FIXATOR

DESCRIPTION

PURPOSE OF THE INVENTION

The present invention relates to a device which has been especially conceived to create a rigidifying bridge between the patient's arm and hand, in order to immobilise his/her wrist, in the event of fracture or dislocation of said wrist, for the entire recovery period during which the joint must be immobilised.

Nevertheless, the device is equally applicable to a single bone, such as for instance the ulna or the radius, when there is this type of fracture.

The purpose of the invention is to allow for easy positional regulation of the two ends of the fixator in order that, once the latter is implanted on the patient's arm and hand, the pertinent regulations may be conducted for the relative position between these elements at the wrist level to be the most suitable.

BACKGROUND OF THE INVENTION

There are known fixators with said purpose, which are also placed on the outer side of the arm and are based on the use of two pairs of nails or screws intended to be fixated to two bones or two parts of a bone, emerging on the outer side of the limb, where each pair of screws or nails receives a fixation block from which a bar transversely emerges; this bar is crowned, in turn, by another block which is substantially distant from the first one, such that the two end blocks are interconnected by means of a third bar, which is perpendicular to the preceding ones and may be fixated by means of stud bolts, thus achieving an essentially rigid structure which stabilises the two elements to be joined.

This solution, which is perfectly valid from the theoretical point of view, in practice leads to problems due to the pronounced distance between the nails that are

inserted into the bone and the longitudinal bar that connects the two pairs of nails, which reduces the stability of the fixation.

On the other hand, even though this device fulfils its function in a basically satisfactory manner when it is intended to immobilise the two portions of a fractured bone, such as for instance the ulna or the radius, it is very difficult to apply, and requires great professional expertise, when the purpose is to immobilise the hand to the arm, due to a wrist problem, since, whereas in the first case it is only necessary for the two bone sectors to be aligned, in the second case, depending on the various types of injuries, the hand must adopt different inclinations or orientations with respect to the forearm.

DESCRIPTION OF THE INVENTION

The external fixator proposed by the invention resolves in a fully satisfactory manner said problems, since it allows for a perfect positional regulation between the two anatomical elements to be joined, after insertion of the nails into them, and not only with respect to closeness/distance, but also with regard to their relative orientation.

More specifically, in order to achieve this, the fixator is structured on the basis of two supports provided with through-holes for respective pairs of the nails used for insertion into the bone; each of these supports is aided by a bearing and a screw-nut set wherein said screw incorporates a head which approaches a spherical annular configuration in order to allow for the passage of a bar which connects said support with a main articulator.

Said through-holes for the nails are laterally open, by means of a narrow slot which, upon closure, causes the support to be fixated to the nails when the screw-nut set is tightened; during this tightening the screw's

spherical head substantially fits into the intermediate bearing, against which the bar laterally presses, thus becoming immobilised.

The main articulator is embodied in an extended body with two identical pitches having a concave internal surface, which are connected by means of a longitudinal slot that opens towards both of the articulator's faces. Two spherical bearings are placed on said pitches; the bars also pass through the bearings, being pressed and immobilised by means of a tightening screw which is transversely mounted on the articulator; the bars' positioning and, consequently, the distance between the supports may be regulated by acting on said tightening screw.

The two spherical bearings have a diametral slot which makes it possible to tighten and/or loosen the bars for their regulation.

As becomes evident, according to the described structuring, the distance between the two end supports may be regulated at will depending on the position of the bars that are fixated to the main articulator, upon tightening thereof, while these bars may form any angle, since they tilt on the main articulator when the latter is in a loose situation and maintain the selected angular position in a perfectly stable manner when it is definitively tightened.

The fixator's special structuring and configuration not only ensure greater mechanical stability, but also make it possible to use plastic materials to obtain certain parts thereof, with the cost reduction this entails.

DESCRIPTION OF THE DRAWINGS

In order to complement the description that is being made, and in order to contribute to a better understanding of the invention's characteristics, in

accordance with an example of preferred embodiment thereof, as integral part of this description a set of drawings is attached, wherein, for illustration purposes, but not limited thereto, the following has been represented:

Figure 1.- Shows a perspective breakdown of the parts of an external wrist fixator embodied in accordance with the purpose of this invention.

Figure 2.- Shows an elevation view of the main articulator which participates in said device.

Figure 3.- Shows a section detail of the same main articulator.

Figure 4.-Shows a cross-section detail of one of the spherical bearings which also participate in the fixator

Figure 5.- Shows a section detail of one of the spherical annular head screws.

Figure 6.- Shows a section detail of one of the bearings which intervenes in each of the device's support sets.

Figure 7.- Shows a cross-section detail of one of the fixation supports for the nails.

Figure 8.- Shows, finally, an example of practical use of the fixator, coupled to a patient's forearm and hand, according to a perspective vision.

PREFERRED EMBODIMENT OF THE INVENTION

In light of said figures, one can observe that the external wrist fixator proposed by the invention is formed by a main articulator (1), embodied in an extended body, which has a pair of identical pitches (2) with a concave internal surface (3), creating a cylindrical segment in each case. Both pitches (2) are connected by a longitudinal slot (4) that opens towards both of the articulator's (1) sides and is located close to one of the articulator's faces, creating two walls (5) and (6) thereon, the first being thicker and having a threaded,

blind hole (7) for a tightening screw (8) that passes through a hole (9) on the thinner wall (6).

Two spherical bearings (10) are placed inside the spherical-segment shaped pitches (2); the bearings have a diametral through-hole (11) and a slot (12) that diametrically connects each hole (11) to the exterior, such that these spherical bearings (10) may be tightened to a greater or lesser extent by means of the screw (8); this tightening is achieved thanks to the slot (12), since tightening of the screw (8) leads to the articulator's (1) walls (5) and (6) coming closer and, thus, the pitches (2) being reduced and, consequently, the spherical bearings (10) being tightened.

One of the bars' (13) ends is housed in the spherical bearings' (10) holes (11); in turn, the bars pass through the main, spherical screws (14), all this in such a way that these bars may be introduced or removed to a greater or lesser extent by simply loosening the tightening screw (8) and performing any of those operations, in order to subsequently fixate it in an undetachable manner by means of the corresponding tightening, as previously mentioned.

In turn, the bars (13) are connected to respective supports (15), which are associated with corresponding bearings (16) provided with a slotted hole (17) in order to allow for tilting, in addition to passage of the threaded shanks (18) pertaining to the spherical screws (14) through them, in addition to the pitch or slotted hole (17), the bearings (16) have a sinkage (19) in the form of a spherical cap, which is intended to partially receive within it the screws' (14) spherical annular head.

The spherical screws' (14) threaded shanks (18), which pass through the bearings' (16) slotted holes (17), in turn pass through another slotted hole (20) provided

on each of the supports (15), with tightening being performed by means of the corresponding nut (21).

The supports (15) have the special feature that the parallel holes (22) intended for passage of the respective nails (23) used for insertion into the bone are laterally open by means of respective slots (24), such that their initial diameter is slightly greater than the nails' (23), in order to act as guides upon insertion of the latter into the bone and, following the fixator's definitive positioning, tightening of the nuts (21) and, more specifically, leaning of the bearings (16) against the supports' (15) concave-curved front (25) when the slots (24) are closed, pinching of the holes (22) against the nails (23), and, consequently, relative immobilisation between these elements.

As has been previously mentioned, and as can be deduced from observing figure 8, the fixator makes it possible for the bars (13) to adopt any necessary angulation to be transmitted to the wrist after having inserted the nails (23) into the bone.

~~, but i~~It may occur that this angular regulation between bars is not necessary, such as for instance in the case of a bone fracture at the forearm level, in which case it is possible to use a single bar; logically, this makes it unnecessary to use the main articulator (1), in which case the ends of said bar are simply mounted on respective sets of spherical screws (14), bearing (16), and support (15).

EXPLANATION SHEET

CLAIMS

1. External wrist fixator which, while being especially conceived to act as a bridging element between the forearm and the hand that immobilises the wrist in any selected position, is characterised in that it is formed by a main articulator (1), whereto a pair of bars (13) are fixated by one end of both bars (13), which are capable of being regulated both longitudinally and angularly; each of ~~which~~ both bars (13) ~~is~~being connected, on the other end, to a support (15), ~~also~~ capable of being longitudinally and angularly regulated, and each of said supports (15) being~~which is~~ provided with a pair of holes (22) for passage of the corresponding nails (23) intended for insertion into the bone; and in

~~2. External wrist fixator, as claimed in claim 1, characterised in~~ that the main articulator (1) is embodied in an extended body provided with a pair of identical pitches (2), whose internal surface is concave, creating cylindrical segments, connected to one another by means of an axial slot (4) which may be narrowed by tightening a transverse screw (8) in order to reduce the corresponding pitches (2), where respective spherical bearings (10) are housed with a diametral pitch (11) that is connected, through a slot (12), with the exterior in order to allow for passage and tightening of the corresponding bar (13), with the latter, in turn, passing through the pitch or hole which the head of a spherical screw (14) has for this purpose, and through which it is linked to the respective support (15).

~~3~~2. External wrist fixator, as claimed in the preceding

h

EXPLANATION SHEET

claims, characterised in that the spherical bearings (10) are located on the pitches (2) with the capacity to rotate around themselves, allowing for the bars' (13) position to be changed in any direction.

~~4~~3. External wrist fixator, as claimed in claim 1, characterised in that the supports' (15) holes (22) are connected to the exterior by means of respective lateral slots (24) which, by allowing a slight lateral oversizing of said holes (22) with respect to the nails (23) intended for insertion into the bone, are pinched over said nails when they are definitively fixated to the ends of the corresponding bars (13).

~~5~~4. External wrist fixator, as claimed in the preceding claims, characterised in that the supports' (15) slots (24) open towards a concave curved face (25) on which a bearing (16) traversed by the spherical annular head screw's (14) threaded shank (18) is adapted; these screws (14) are complemented by respective nuts (21).

~~6. External wrist fixator, as claimed in claim 1, characterised in that, in a simple version, it does not require intermediate articulation in the fixator; the latter is structured by means of a single bar (13) whereto respective sets, capable of being longitudinally regulated, of spherical annular head screws (14), bearing (16), support (15), and nut (17) are fixated to the ends.~~

1/4

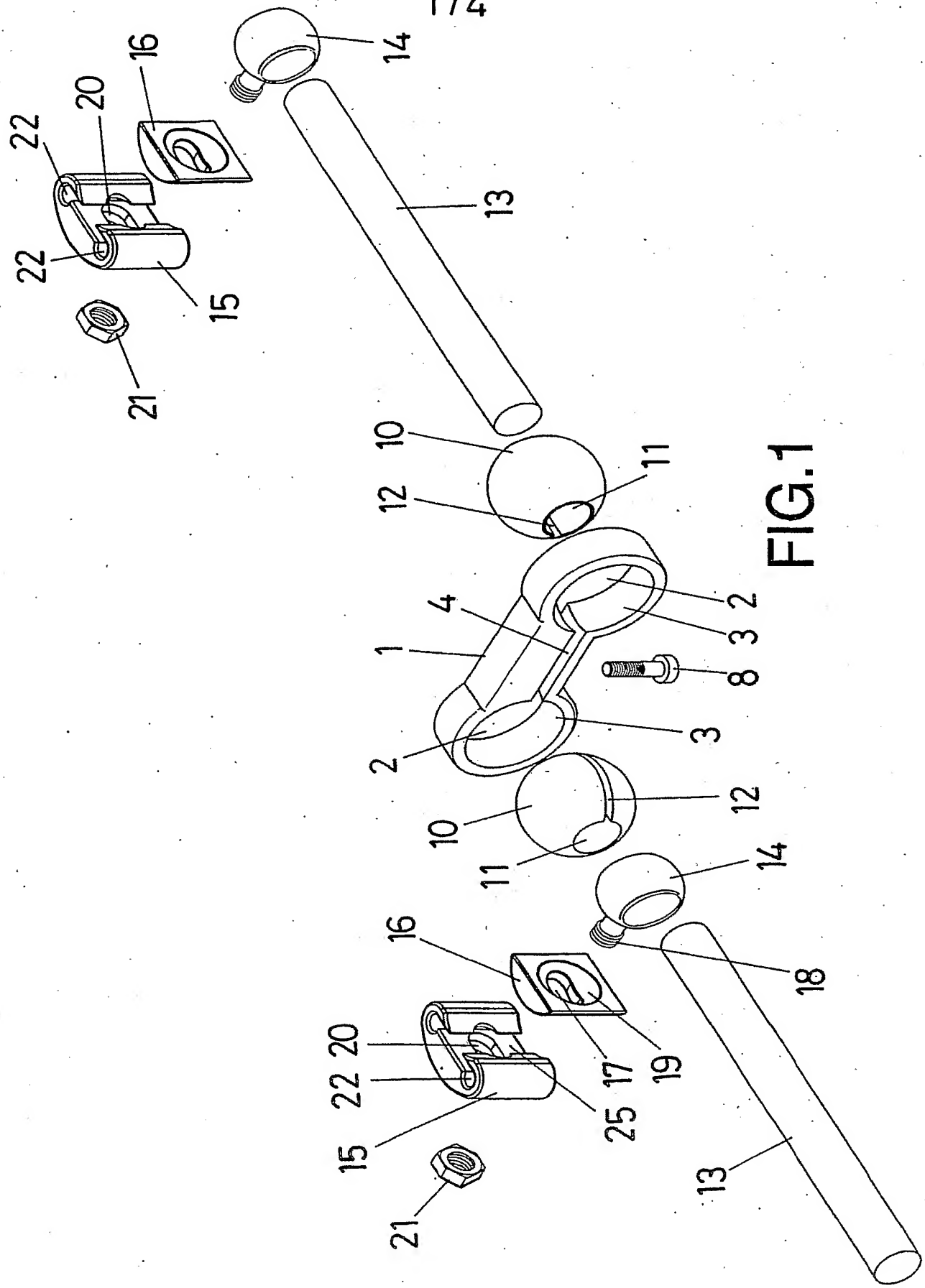
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FIG.1

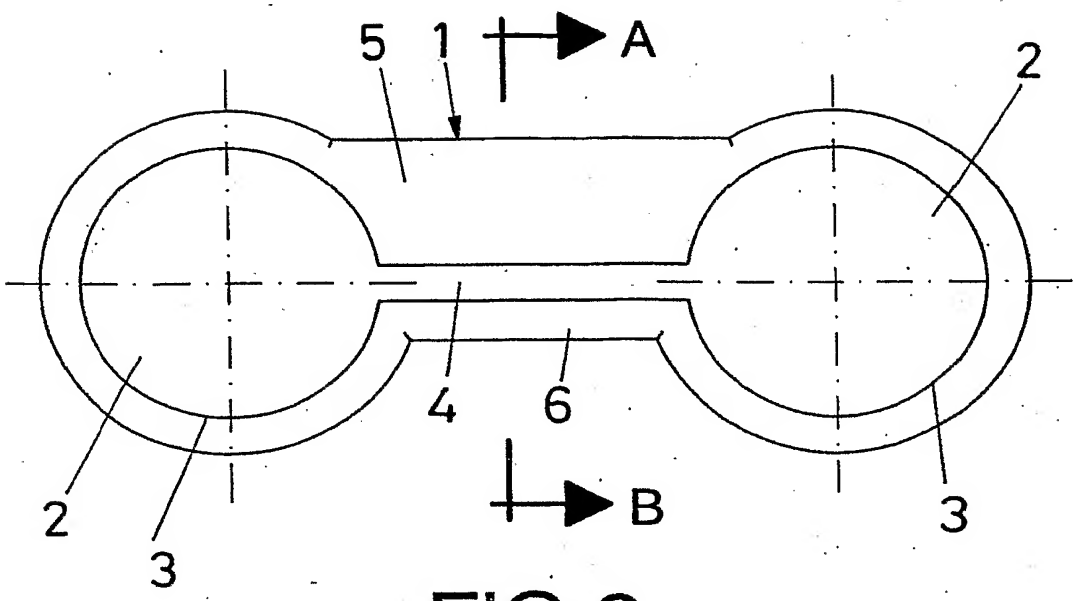

FIG.2

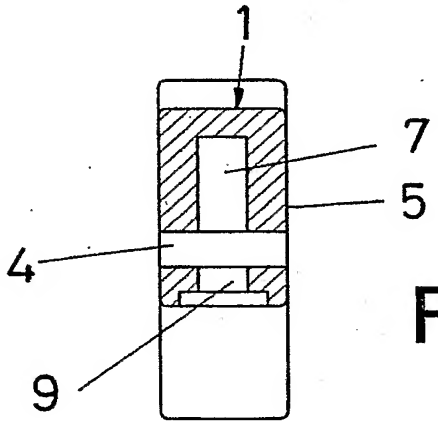

FIG.3
A-B

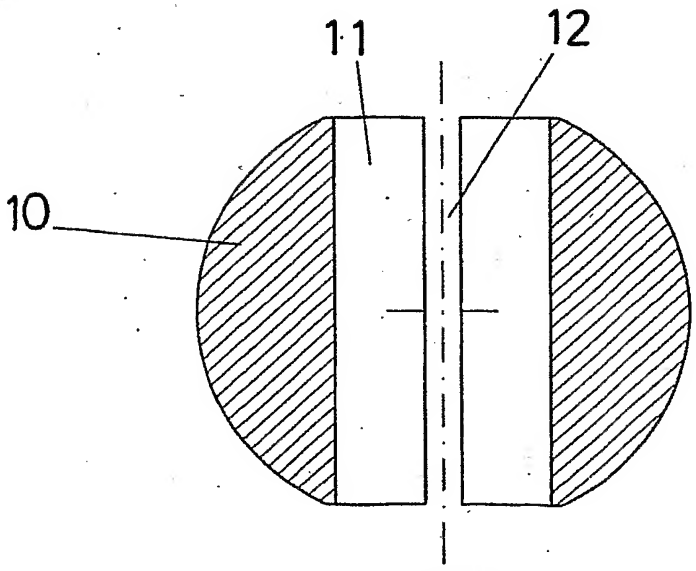

FIG.4

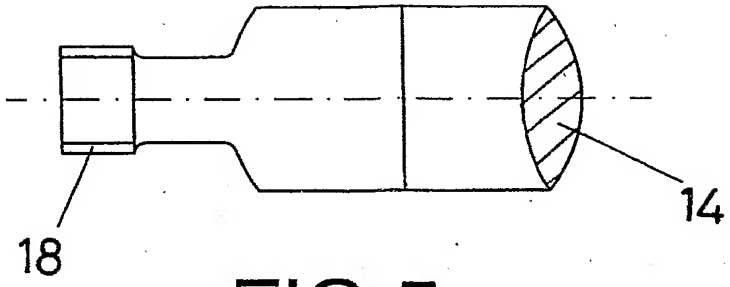

FIG.5

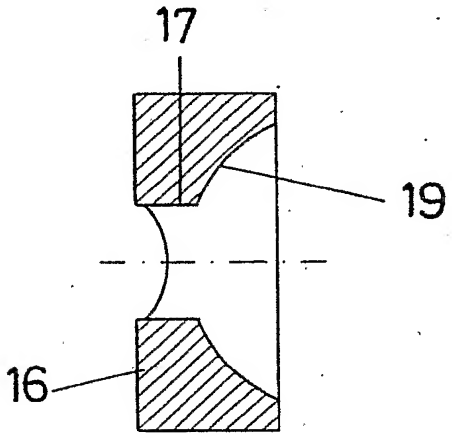

FIG.6

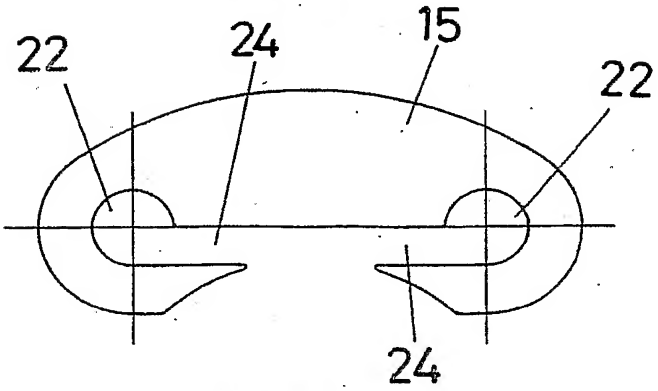

FIG.7

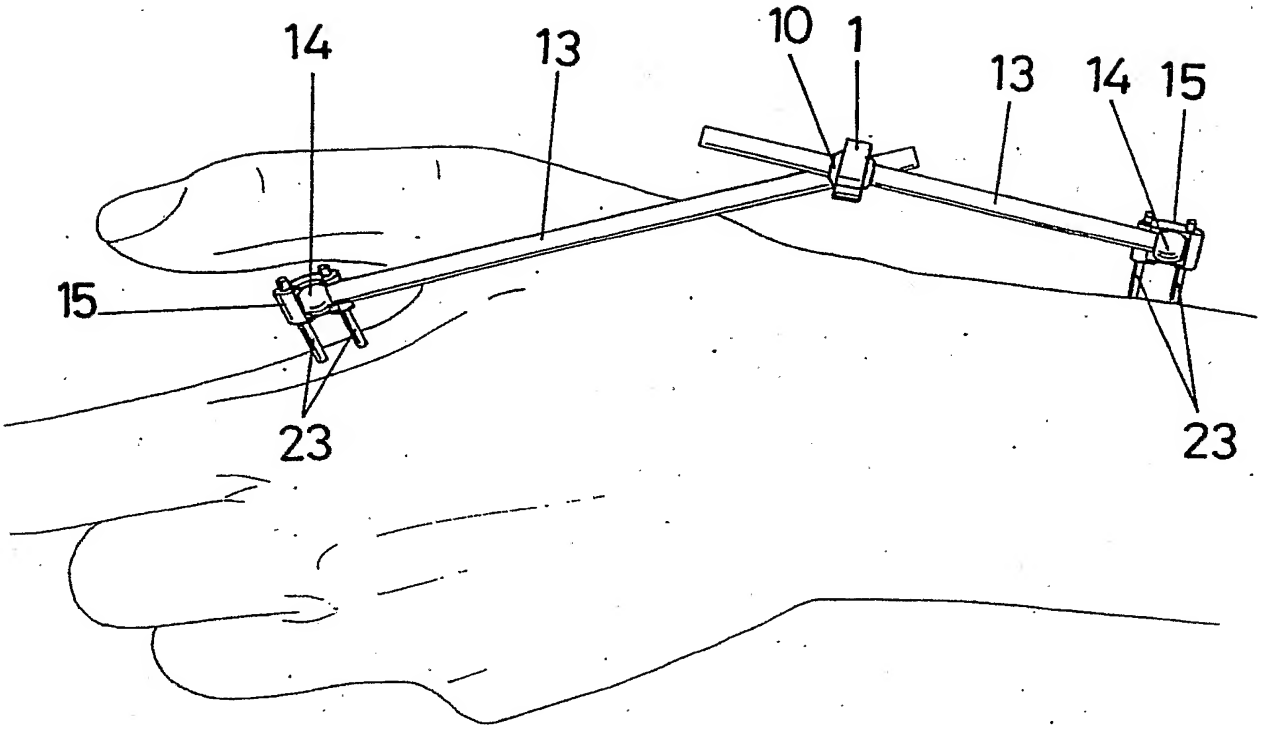

FIG.8